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EXAMINER	
KERR, J	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/185,243	Applicant(s) TSANG ET AL.	
	Examiner Janet Kerr	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-7,9-18,20-26,33,35-39,41 and 43-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1,5-7,9-18,20-26,33,35-39,41 and 43-46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

Response to Amendment

Applicants' amendment, filed 12/28/00, has been entered.

Claims 2-4, 8, 19, 27-32, 34, 40, and 42 have been canceled.

Claims 1, 5-7, 9-18, 20-26, 33, 35-39, 41, and 43-46 remain pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1, 2, 7, and 39-41 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record and the reasons below.

Applicant's arguments filed 12/28/00 have been fully considered but they are not persuasive. It is argued that the specification provides sufficient written description of HSP28, HSP72 or HSP73 as the specification has extensively described various promoters and promoter control regions and the use of the HSP 70 promoter in order to induce expression of a reporter gene. Applicants argue that (1) the description clearly allows persons of ordinary skill in the art to recognize that he or she invented what is claimed, relying on *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1991), that (2) the applicant conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed, relying on *Vas-Cath, In. v Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), and that the examiner has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by

the claims (see page 8 of applicants' Response). It is asserted that applicants were in possession of the necessary common features of the elements possessed by HSP70, HSP90, HSP60, HSP27, HSP72, HSP73, HSP25, ubiquitin, and HSP28 as disclosed in the invention. It is also asserted that the promoter regions of HSP28, HSP72 or HSP73 were known in the art as evidenced by the teachings of Hastie *et al.*, Zhou *et al.*, and Lee *et al.* (see page 9 of applicants' Response).

These arguments are not persuasive as the specification does not disclose any promoter sequences of HSP28, HSP72 or HSP73, nor does the specification disclose the necessary common features of the promoter elements which render the promoter inducible under the claimed conditions. Given that the structural features of these promoters have not been disclosed in the specification, and as applicants have not provided any objective evidence that they were in possession of these promoters, these arguments are not persuasive. While applicants assert that Hastie *et al.*, Zhou *et al.*, and Lee *et al.* Teach the necessary promoter elements of HSP28, HSP72 or HSP73 which render the promoter inducible under the claimed conditions, applicants have not provided a copy of these references. The examiner will consider the teachings of these references upon receipt of these references by applicants.

As there is no disclosure of the HSP28, HSP72 or HSP73 promoter sequences required for the invention, the skilled artisan cannot envision the detailed chemical structure of the encompassed nucleic acid sequences, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

The limited information provided in the specification is not deemed sufficient to reasonably convey to one skilled in the art that Applicants were in possession of the HSP28, HSP72 or HSP73 promoter sequences, *per se*, or control regions of HSP28, HSP72 or HSP73 promoters which render the promoters inducible under the claim-designated conditions.

Claims 1, 5-7, 9, 18, 20-26, 33, and 35-38 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an expression construct comprising the inducible promoters, HSP70, HSP90, HSP60, HSP27, HSP25, and ubiquitin, operably linked to a gene encoding a transactivating factor and a second promoter operably linked to a selected polynucleotide, wherein the second promoter is activated by a transactivating factor, and a method of effecting expression of a selected polynucleotide in a mammalian cell, *in vitro*, comprising introducing the expression construct into a mammalian cell, and subjecting the mammalian cell, *in vitro*, to hyperthermic conditions, does not reasonably provide enablement for expression constructs comprising the inducible promoters, HSP28, HSP72 or HSP73, or *in vivo* methods of using the expression constructs comprising these promoters, i.e., a method of providing a subject with a therapeutically effective amount of an expression product of the selected polynucleotide by introducing the expression construct into a mammalian cell; a method of treating cancer in a mammal by introducing the expression construct into a mammalian cell; a method of provoking an immune response in a mammal, or a method of altering the genetic material of a mammal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Applicant's arguments filed 12/28/00 have been fully considered but they are not persuasive. It is argued that applicants' claimed invention should not be limited to the showings in the specification, that the specification explicitly states that any inducible promoter may be used in the practice of the present invention, that applicants have correlated the *in vitro* effect of the heat shock promoter with the *in vivo* effect as disclosed in Example 4 of the instant application, that applicants are not required to provide specific examples of all possible embodiments, and that the examiner has not supplied convincing reasons why one skilled in the art would not be able to practice the invention in light of the teachings in the specification (see page 12 of applicants' Response). It is further argued that with regard to gene therapy, the art of gene therapy has

rapidly progressed since 1995 and continues to do so, and further, that the question of "clinical efficacy" is not relevant with respect to patent laws (see page 13 of applicants' Response).

These arguments are not persuasive. With regard to the HSP28, HSP72 or HSP73 promoters, as stated above, applicants have not shown how to make the promoters such that they can be used in the expression constructs. With regard to the correlation of *in vitro* and *in vivo* data, Example 4 is a prophetic example. There is no data to support applicants' assertion that applicants have correlated an *in vitro* effect with an *in vivo* effect. With regard to the state of the art of gene therapy, applicants imply that the examiner has only provided one reference, i.e., the 1995 Orkin *et al.* reference, to support the examiner's position that gene therapy is unpredictable. It should be noted that he examiner has cited numerous references, e.g., Orkin *et al.*, (December 1995), Ledley (1996), Verma *et al.* (1997), Gura (1997), Gomez-Navarro *et al.* (1999), and Leitner *et al.* (2000) to address the unpredictability issues of providing constructs, *in vivo*, with regard to tissue targeting, expression levels, and therapeutic/clinical efficacy. These references clearly teach that providing a gene to an animal *in vivo* to obtain a requisite effect is neither routine nor predictable. Thus, for the reasons of record, and the reasons set forth above, the rejection is maintained.

Claims 7 and 41 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's arguments filed 12/28/00 have been fully considered but they are not persuasive. It is argued that the recitation of HSP28, HSP72, and HSP73 promoters is not vague and indefinite as the specification discloses the promoters required for the invention, that the promoters are known in the art, and that the claims are not flawed claims, but rather broad claims.

These arguments are not persuasive for the reasons set forth under the 35 U.S.C. 112, first paragraph rejections. There is no disclosure of these sequences, thus it is unclear what sequences are encompassed in the claim. Applicants have not provided the references which applicants

assert teach the promoter regions of the claimed invention. The metes and bound of the claim are unclear as it is unclear what the structural features of the promoters are. Breadth is not being equated with indefiniteness. Applicants have not defined the structures of these promoters, thus the claims are indefinite. For the reasons of record and the reasons set forth above, the rejections are maintained.

Claim Rejections - 35 USC § 102

Claims 1, 5-7, 10-12, 14, 16, 39-40, 43, 44, and 46 remain rejected under 35 U.S.C. 102(b) as being anticipated by Bromley *et al.* (EP 0299127, 1989) for the reasons of record and the reasons below.

Applicant's arguments filed 12/28/00 have been fully considered but they are not persuasive. It is argued that the advantage of the heat shock (hsp) promoter used in the instant advantage is the activation of the hsp promoter at temperatures below 42°C, and that achieving uniform temperatures above 42°C in tumors is difficult and not often possible. Applicants refer to teachings in the specification that the HSP-70 promoter used in the disclosed constructs drives expression at a temperature as low as 37°C. Applicants assert that the hsp promoter disclosed in the specification is activated at basal temperatures, which is clearly a novel and unprecedented achievement (see pages 15-16 of applicants' Response).

These arguments are not persuasive as applicants are arguing limitations which are not in the claimed invention. Claims 1 and 39 recite activation of the hsp promoter at temperatures between "about 37°C and about 42°C". Claim 5 recites that the activation temperatures are between "about 38°C and about 41°C". Claim 6 recites that the activation temperatures are between "about 39°C and about 40°C". Bromley *et al.* teach activation of the hsp promoter at 42.5°C and 43°C, and as stated in the previous office action, the taught activation temperatures are not distinguishable from the claimed temperatures of "about 40°C", "about 41°C" and "about 42°C".

It is argued that Bromley *et al.* do not disclose or teach a construct where the hybrid genes are on one vector, and as such, they do not enable one skilled in the art to make or do the same (see page 16 of applicants' Response). This is not persuasive. As set forth in the previous office action, Bromley *et al.* teach the hybrid genes can be part of one or separate vectors (see pages 3-6 of Bromley *et al.* for teachings of the construct components). Applicants have not provided any objective evidence as to why one of skill in the art could not make the constructs of Bromley *et al.*

With regard to applicants arguments that the constructs of the invention are different from those of Bromley *et al.* (see page 16 of applicants' Response), it should be noted that the constructs of the claimed invention and the taught invention are the same. The claimed invention does not recite specific constructs such as pC8, pf12 and p007, nor doe the claims recite constructs comprising specific regulatory and non-regulatory linking sequences. Thus, applicants' arguments are not persuasive.

Applicants rely on *In re Royka and Martin, 180 USPQ 580 (CCPA 1974), Mendenhall v Astec Industries, Inc., 13 USPQ.2d 1913, 1928 (Tenn. 1988), aff'd, 13 USPQ.2d 1956 (Fed. Cir. 1989)*, and *Glaverbel Societe Anonyme v Northlake Marketing & Supply Inc., 45 F.3d 1550, 33 USPQ.2d 1496, 1498 (Fed. Cir. 1995)* to support applicants' argument that Bromley *et al.* fail to teach, either expressly or inherently the claimed method (see pages 16-17 of applicants' Response). This is not persuasive as Bromley *et al.* clearly teach the components of the vector of the instant invention and the method of using the vector (see page 15 of the Office action of 6/26/00). For the reasons of record and the reasons stated above, the rejection is maintained.

In view of applicants' amendment to the claims, the 35 U.S.C. 102(e) rejection of claims 1, 10, 12, 13, 15, 16, 39, and 44-46 as being anticipated by Gage *et al.* has been withdrawn.

Claim Rejections - 35 USC § 103

Claims 1, 10, 12, 13, 15, 16, 39, and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bromley *et al.* (of record) taken with Gage *et al.* (of record). This rejection is newly applied in view of applicants' amendment to the claims.

Gage *et al.* teach an expression construct comprising an inducible promoter operably linked to a gene encoding a transactivating factor, a second promoter operably linked to the selected polynucleotide which is a protein, wherein the second promoter is activated by the transactivating factor, a gene encoding a selectable marker, and an internal ribosome entry site positioned between a first and second selected polynucleotide (see, e.g., col. 4, lines 21-65, col. 5, lines 17-48, and Figure 1). Gage *et al.* further teach introducing the expression construct into neuronal progenitor cells, *in vitro*, wherein the introduction of the expression construct is mediated by a retroviral vector, to obtain expression of the selected polynucleotides (see, e.g., col. 6, lines 29-41, and Examples 3 and 4).

Gage *et al.* do not teach using a heat shock promoter in the expression construct. However, Bromley *et al.* teach modified inducible hybrid genes, i.e., expression constructs comprising 1) genes of interest operably linked to HIV LTR promoter sequences and 2) a tat-III gene operably linked to a heat shock promoter (see page 3, lines 51-58, and page 4, lines 1-5), such as the hsp70 promoter (see, e.g., pages 5 and 6 under "Plasmid Construction"). The constructs can be introduced into host cells in the form of plasmid vectors and the constructs and vectors can comprise either one or both of the genes of interest operably linked to HIV LTR promoter sequences and 2) a tat-III gene operably linked to a human heat shock promoter, and can further comprise a selectable marker (see, e.g., page 4, lines 1-3, and lines 22-31, page 5, lines 1-3, and claims 1, 9, and 10). The hybrid genes can be part of one or separate vectors whereby incorporation into host cells is carried out by transfection or co-transfection (see, e.g., page 4, lines 28-29). Numerous genes of interest can be incorporated into the vector system (see, e.g., page 4, lines 17-21). The inducible hsp promoter is activated by hyperthermic conditions and expression of the hybrid constructs is observed at 42.5°C or 43°C (which can be considered about

40°C or 41°C or 42°C). See, e.g., page 6, lines 24-29, and Tables 1-3. Bromley *et al.* teach that the advantage of this inducible expression construct is that a substantially prolonged time of expression is observed upon a single heat activation cycle whereas in non-hybrid inducible expression constructs, multiple cycles of heat activation are required for continued expression of the construct which is technically inconvenient and may result in cell growth inhibition and subsequent cell death (see, e.g., page 2, lines 34-39, and page 3, lines 6-23).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the expression construct of Gage *et al.* by substituting the inducible promoter of Gage *et al.* with the inducible heat shock promoter of Bromley *et al.* in view of the advantages of the promoter taught by Bromley *et al.*, e.g., a substantially prolonged time of expression induced by a single heat activation cycle which would minimize cell growth inhibition and subsequent cell death which would be observed with multiple cycles of heat activation. Moreover, as substituting vector components was well known in the art of molecular biology, it would have been well within the purview of substituting one type of inducible promoter for another to provide a vector with recognized advantages.

Thus the claimed invention as a whole was clearly *prima facie* obvious at the time the claimed invention was made especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Claims 1, 7, 39, and 41 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bromley *et al.*, taken with any one of Stover, Hickey *et al.*, Gaestel *et al.*, Dale *et al.*, or Quail *et al.* for the reasons of record and the reasons below.

Applicant's arguments filed 12/28/00 have been fully considered but they are not persuasive. It is argued that the amendments to the claims clearly distinguish the invention from Bromley *et al.* for reasons discussed under the 35 U.S.C. 102(b) rejection. Applicants assert that the Bromley *et al.* reference is no longer a relevant reference in combination with the other

references cited (see page 20 of applicants' Response). This argument is not persuasive for the reasons discussed above.

It is also argued that heat shock promoters of the instant invention can be activated at temperatures as low as 37°C are clearly novel and unobvious (see pages 20-21 of applicants' Response). This argument is not persuasive as applicants are arguing limitations not recited in the claimed invention. As stated above, the reference activation temperatures of Bromley *et al.* are not distinguishable from the claimed temperatures of "about 40°C", "about 41°C" and "about 42°C". For the reasons of record and the reasons stated above, the rejection is maintained.

The rejection of claims 1, 8, 39, and 42 under 35 U.S.C. 103(a) as being unpatentable over Bromley *et al.*, taken with either Webster *et al.*, or Dachs *et al.* has been withdrawn in view of applicants' cancellation of claims 8, 19, and 42. The examiner wishes to apologize for citing claim 39 as opposed to claim 19 in this rejection. This was an obvious typographical error as the rejection was directed to hypoxia-responsive promoter elements, a limitation recited in claim 19 and not claim 39.

Applicants arguments have been fully considered but are moot in view of the cancellation of claims 8, 19, and 42.

Claims 1, 10, 11, 39, and 44 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bromley *et al.*, taken with any one of Dubensky Jr. *et al.*, Scott *et al.*, Saito *et al.*, Weinberg *et al.*, Beach *et al.*, or Tweari *et al.*, for the reasons of record and the reasons below.

Applicant's arguments filed 12/28/00 have been fully considered but they are not persuasive. Applicants argue that the construct disclosed in Bromley *et al.* is not identical to the instant invention as previously discussed. This argument is not persuasive for the reasons set forth above.

Applicants refer to *Hybritech Inc. V Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81, 93 (Fed. Cir. 1986) arguing that focusing on the obviousness of substitutions and differences instead of the invention as a whole is a legally improper way to simplify the difficult determination of obviousness. This is not persuasive. Bromley *et al.* teach a vector system which comprises the claim-designated elements with the exception of specific claim-designated proteins of interest. However, Bromley *et al.* clearly teach that the gene of interest in the vector system can readily be substituted. For example, Bromley *et al.* teach that the gene of interest includes genes encoding viral antigens, blood factors, hormones, enzymatically active proteins, structural proteins, proteins for diagnostic tests such as TNF and interleukin, and other products of clinical and pharmaceutical interest. Dubensky *et al.* teach that genes of interest which can be expressed recombinantly include the claim-designated specific interleukins, specific interferons, TNF, etc. Similarly, Scott *et al.*, Saito *et al.*, Weinberg *et al.*, and Beach *et al.* teach recombinant expression of the claim-designated proteins. Given that the vector is taught in the art, and the genes of interest are taught in the art, one of ordinary skill would have had a high expectation of successfully modifying a known vector by substituting a known gene encoding a protein of interest. As expression of the claim-designated proteins by recombinant methods are clearly known in the art, one of ordinary skill would have been motivated to express these proteins in the vector of Bromley *et al.* in view of the teachings of Bromley *et al.* that expression of the proteins using the vector can be suitably regulated by environmental conditions. For the reasons of record and the reasons stated above, the rejection is maintained.

Claims 1 and 15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bromley *et al.*, taken with any one of Loeb *et al.*, Hancock, or Talavera *et al.*, for the reasons of record and the reasons below.

Applicant's arguments filed 12/28/00 have been fully considered but they are not persuasive. Applicants argue that the construct disclosed in Bromley *et al.* is not identical to the instant invention as previously discussed (see page 25 of applicants' Response). This argument is

not persuasive for the reasons set forth above. Applicants further argue that neither Bromley *et al.*, taken alone, or in combination with the secondary references could have taught the superiority of the claimed expression constructs containing the heat shock promoters, or the methods of effecting expression via these expression constructs for any type of expression (see page 26 of applicants' Response). This is not persuasive for the reasons set forth above. The reference activation temperatures of Bromley *et al.* are not distinguishable from the claimed temperatures of "about 40°C", "about 41°C" and "about 42°C".

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning (see page 25 of applicants' Response), it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, Bromley *et al.* clearly teach the claim-designated thermoinducible construct. It is well known in the art that constructs can be introduced into a cell by any of the well recognized gene transfer systems taught by Loeb *et al.*, Hancock, or Talavera *et al.* One of ordinary skill in the art would have had a high expectation of successfully introducing the construct of Bromley *et al.* by the means taught by Loeb *et al.*, Hancock, or Talavera *et al.* barring evidence to the contrary. For the reasons of record and the reasons stated above, the rejection is maintained.

Sequence Compliance

Applicants' arguments with regard to compliance with the requirements of 37 CFR 1.821(d) are not persuasive (see page 27 of applicants' Response). 37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences. See MPEP 2422.03.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet M. Kerr whose telephone number is (703) 305-4055. Should the examiner be unavailable, inquiries should be directed to Deborah Clark, Supervisory Primary Examiner of Art Unit 1633, at (703) 305-4051. Any administrative or procedural questions should be directed to Kimberly Davis, Patent Analyst, at (703) 305-3015. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-7401.

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